

Remarks

Claims 1-17 were pending in the subject application. By this Amendment, the applicants have amended claims 1, 2 and 16, have cancelled claims 15 and 17 and added new claim 18. Further, the applicants have withdrawn claims 3-14 as being drawn to non-elected subject matter. The applicants have also amended withdrawn claims 3-7, 9, 12 and 13. Accordingly, claims 1, 2, 16 and 18 are pending in the subject application. No new matter has been added by these amendments.

The amendments and claim cancellations set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claim 16 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 16 has been amended herein to address the issue identified by the Examiner. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph.

Claims 1, 2 and 17 have been rejected under 35 U.S.C. §112, first paragraph. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

The applicants respectfully submit that they were in full possession of the claimed subject matter and that the requirements of 35 U.S.C. §112, first paragraph have been met.

The test for an adequate written description has been stated in a variety of ways. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention,

in that context, is whatever is now claimed. It is respectfully submitted that the applicants have met this test given the teachings of the specification and the scope of the claims.

Please note that, in order to expedite prosecution, the claims have been amended herein so that they no longer recite “prevention.” Also, claim 17 has been cancelled herein. For the reasons set forth above, the applicants believe that they have fulfilled the requirements of 35 USC §112.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Holen, APMIS, 1998, pages 849-857, Vol. 106. The applicants respectfully traverse this ground for rejection because the cited reference does not disclose the subject matter as set forth in the claims as amended herein.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Please note that claim 1 has been amended herein to remove reference to fenoterol.

The cited reference does not disclose each and every element of the invention as now claimed. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Holen reference.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,086,363 (Cervoni). The applicants respectfully traverse this ground for rejection because the cited reference does not disclose the subject matter as set forth in the claims as amended herein.

The applicants respectfully point out that for a claim to be anticipated under the principles of inherency, the subject of a single prior art reference must necessarily function in accordance with the limitations of the process or method claimed. *In re King*, 801 F2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further,

the doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation. . . . A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-33 (E.D. KY 1988).

The Cervoni reference does not disclose with certainty the use of nylidrin to treat a condition associated with T-cell proliferation or that is mediated by pro- and/or anti-inflammatory cytokines.

Thus, the cited reference does not disclose each and every element of the invention as now claimed. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Cervoni reference.

Claims 2 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,086,363 (Cervoni) as applied above, and further in view of WO 03/092617 (Jost-Price *et al.*). The applicants respectfully traverse this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the applicants' claimed method for treating rheumatoid arthritis, osteoarthritis or osteoporosis.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007). Furthermore, an applicant's invention is not "proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art." *Id.*

The Court of Customs and Patent Appeals was faced with an analogous situation in *In re Hayashibara and Sugimoto*, 188 USPQ 4 (CCPA 1975). The PTO Board of Appeals had affirmed a §103 rejection, and the CCPA reversed, stating:

Turning to the . . . rejection . . . for obviousness under 103, we agree with appellants that there is nothing in the reference which would lead those of ordinary skill in the art to employ [the substance] as appellants do in the product of claim 11. The reference does not teach [the substance] as possessing any of the characteristics or functions upon which appellants' claimed invention depends (emphasis added).

Please note that claim 17 has been cancelled herein in order to expedite prosecution.

The deficiencies of the primary Cervoni reference with respect to the current invention have been discussed above. The Jost-Price *et al.* reference does not cure these deficiencies.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on Cervoni and Jost-Price *et al.*

Please note the addition of new claim 18, which incorporates the limitations of previous claim 16, to which no prior art rejection was applied. The applicants respectfully submit that new claim 18 and the other pending claims are in condition for allowance.

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik

Patent Attorney

Registration No. 31,794

Phone No.: 352-375-8100

Address: P.O. Box 142950  
Gainesville, FL 32614-2950

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